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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/092,033   | 03/05/2002  | Stephen F. Fulghum   | NLI-002AX           | 7761             |
| 207 7590 01/04/2010<br>WEINGARTEN, SCHURGIN, GAGNEBIN & LEBOVICI LLP |             | EXAMINER             |                     |                  |
| TEN POST OFFICE SQUARE   |             |                      | LEUBECKER, JOHN P   |                  |
| BOSTON, MA 02109   |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3739                |                  |
|  |             |                      |                     |                  |
|  |             |                      | MAIL DATE           | DELIVERY MODE    |
|  |             |                      | 01/04/2010          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.  | Applicant(s)        |  |  |  |
|--|--|---------------------|--|--|--|
| Office Action Summers  | 10/092,033   | FULGHUM, STEPHEN F. |  |  |  |
| Office Action Summary  | Examiner   | Art Unit            |  |  |  |
|  | John P. Leubecker  | 3739                |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply  |  |                     |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                     |  |  |  |
| Status   |  |                     |  |  |  |
| 1) Responsive to communication(s) filed on 20 M  | ovember 2009 and 23 December   | 2009                |  |  |  |
|  | Responsive to communication(s) filed on <u>20 November 2009 and 23 December 2009</u> .  This action is <b>FINAL</b> .  2b) This action is non-final. |                     |  |  |  |
| <i>,</i> —   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is                                      |                     |  |  |  |
| •  | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |                     |  |  |  |
| closed in accordance with the practice under Ex pane Quayle, 1935 C.D. 11, 455 C.G. 215.   |  |                     |  |  |  |
| Disposition of Claims  |  |                     |  |  |  |
| 4) Claim(s) 1-11,21-26 and 36-50 is/are pending  | )⊠ Claim(s) <u>1-11,21-26 and 36-50</u> is/are pending in the application.   |                     |  |  |  |
|  | 4a) Of the above claim(s) is/are withdrawn from consideration.   |                     |  |  |  |
| 5) Claim(s) is/are allowed.  |  |                     |  |  |  |
| 6)⊠ Claim(s) <u>1-11,21-26 and 36-50</u> is/are rejected.  |  |                     |  |  |  |
| 7) Claim(s) is/are objected to.  |  |                     |  |  |  |
| 8) Claim(s) are subject to restriction and/o   | r election requirement.  |                     |  |  |  |
| o) Claim(3) are subject to restriction and/or election requirement.  |  |                     |  |  |  |
| Application Papers   |  |                     |  |  |  |
| 9)☐ The specification is objected to by the Examiner.  |  |                     |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |  |                     |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |                     |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |  |                     |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |  |                     |  |  |  |
| Priority under 35 U.S.C. § 119   |  |                     |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |  |                     |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/23/09.  | 4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other:  | te                  |  |  |  |

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### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 20, 2009 has been entered.

# Claim Objections

2. Claims 41-49 are objected to because of the following informalities: There are two claims numbered as "41" in the amendment filed December 23, 2009. For purposes of examination, the second claim 41 will be enumerated as claim 42 and all subsequent claims will be numbered accordingly (the highest claim number will be 50). Appropriate correction is required in the next response (note that only the dependency of claim 49 will have to be changed).

### Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described

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in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Two types of light are referred to a "reference light" in the application: normal white (e.g. red,green,blue) light used for the normal visible light image and red/infrared light used as a reference light for comparison purposes. Both are confusingly mentioned using the term "reference light" but **only one** is disclosed as being emitted simultaneously with the excitation light (as required by claim 7). The reference light of red/infrared wavelengths is the one that can be emitted simultaneously with the excitation light. The reference light including red, green and blue wavelengths (which corresponds to the normal image light mode and is the "reference light" claimed in claim 1) is not disclosed as being capable of being emitted simultaneously with the excitation light. In other words, the specification fails to disclose simultaneous transmission of excitation light and a light comprising red, blue and green wavelengths (e.g., white light).

Although a white light source is disclosed, light from this source is filtered to exclude <u>all of</u> red, blue and green wavelengths from being simultaneously transmitted with the excitation light.

- 5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 6. Claims 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 36, term "the endoscope" (line 15) lacks antecedent basis.

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As to claim 37, term "said combined light" (line 8) and "the combined light" (line 9) lack antecedent basis since only "optically coupled" light is previously claimed.

# Claim Rejections - 35 USC § 103

- 7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 8. Claims 1-6, 8-11, 21, 23, 24 and 36-42, 44-50<sup>1</sup> are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al. (U.S. Pat. 5,749,830) in view of Poindexter et al. (U.S. Pat. 5,979,523).

Referring mainly to Figure 51, Kaneko et al. disclose a laser light source (904) for producing light having a wavelength in a range of 300 to 420 nm (col.7, lines 35-38), a second light source (905), an optical combiner (915,916), a common optical path coupled to an optical guide (901), a single image detector (902), and a data processor (908,913). Although Kaneko et al. discloses a He-Cd laser as an example of just one source that operates in the necessary wavelength range, a diode laser light source is not mentioned. However, certain diode laser light sources are known to operate in the wavelength range of 300 to 500 nm. Poindexter et al. is just one example of a teaching that a GaN diode laser, which operates within the claimed wavelength range, is a suitable source of excitation light (col.2, lines 57-67) in a fluorescence detection system (col.3, lines 35-41). Since both references teach types of laser light sources for inducing fluorescence, it would have been obvious to one of ordinary skill in the art to substitute one type

of laser light source for the other to achieve the predictable result of providing excitation light.

One would be motivated to use a diode laser over a conventional laser or other light source due to its efficient, low power and stable emission of light.

Furthermore, the transmission of light by the light sources of Kaneko et al. are enabled/disabled (e.g., operable) by signals from a timing controller (907) and computer (941), both of which would anticipated a control system.

As to claim 5, note that the CCD is at the distal tip of the endoscope. Kaneko et al. also discloses in Figure 51 the situation where a sequential RGB light (note filter 918) is used with a monochromatic CCD. However, earlier in the reference, Kaneko et al. explicitly teaches that use of a simultaneous RGB (white) light with a color CCD is alternatively and equivalently used to produce the same results (note Figures 4a and 4b, col.9, lines 6-9 and col.12, lines 20-33). Since both methods are known in the art, it would be within the level of ordinary skill in the art to use either as an alternative to one another, and Kaneko et al. contemplates both for use in the disclosed fluorescence endoscope system, it would have been obvious to one of ordinary skill in the art to have modified the embodiment of Figure 51 to have used a color CCD. Where there is a limited universe of potential options, the selection of any particular option would have been obvious to one of ordinary skill in the art. In re Jones, 412 F.2d 241, 162 USPQ 224 (CCPA 1969).

As to claim 36, note the rejection of Kaneko et al. and Poindexter et al. above with respect to claim 1. Poindexter et al. specify the use of a gallium nitride diode laser. In addition,

<sup>&</sup>lt;sup>1</sup> Note that the second occurrence of claim 41 to claim 49 have been renumbered in this Office Action as claims 42-50.

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Kaneko et al. correlate the optical guide (901) to an optical fiber delivery system (e.g., col.41, lines 1-2).

As to claim 37, note rejection of Kaneko et al. and Poindexter et al. above with respect to claim 1.

As to claims 2 and 38, note superimpose circuit (928, col.62, lines 61-67). As to claims 3 39 and 40, note that the solid state imaging element (902) can be a CCD (note at least col.21, line 64). As to claims 4 and 41, note (831) in Figure 49. As to claims 6 and 42, note column 63, lines 19-27. Since the excitation light and reference light are sequentially transmitted (by 916), claim 8 is met. As to claim 9, note red filter in RGB filter (918). As to claims 10 and 44, note (920). As to claims 11 and 45, since the reference and excitation lights share a common optical path, they have the same angular distribution. As to claims 21 and 46, a CCD is pixellated. As to claims 23, 24 and 48, obvious choice of the diode laser source as taught by Poindexter et al. would meet these limitations.

9. Claims 22 and 47<sup>1</sup> are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al. in view of Poindexter et al. and further in view of Perelman et al. (U.S. Pat. 6,091,984).

Kaneko et al. teach a device that uses, for example a CCD, for the image sensor but fails to disclose all other known image sensors that can alternatively used. Perelman et al. teaches what is known by all of those of ordinary skill—the alternative use of either a CCD or CMOS image sensor (note col. 4, lines 26-34). CMOS technology is not new and in certain arrangements has cost advantages and improved functionality over CCD technology. It would

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therefore have been obvious to one of ordinary skill in the art to have used a CMOS image sensor instead of a CCD image sensor for the reasons set forth above.

10. Claims 25, 26, 49 and 50<sup>1</sup> are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al. in view of Poindexter et al. and further in view of Groner et al. (U.S. Pat. 6,104,939).

Kaneko et al. provides reference to a xenon light source *as an example* (note col.7, line 31). Groner et al. also teaches use of a xenon light source in addition to many alternatives including a mercury arc lamp and a laser diode (col. 24, line 55 to col.25, line 4). It would have been obvious to one of ordinary skill in the art as a matter of design choice to use any known alternative type of light source as taught by Groner et al.

11. Claims 37-41, 43, 45 and 46<sup>1</sup> are rejected under 35 U.S.C. 103(a) as being unpatentable over Palcic et al. (U.S. 5,827,190) in view of Imaizumi et al. (U.S. Pat. 6,293,911).

Palcic et al. disclose a fluorescence imaging endoscope system comprising a light source for producing excitation light having a wavelength in the range of 380 to 420 nm and a second light source (8,30) (col.5, lines 13-22, col.9, line 59 to col.10, line 2), an optical combiner (inherent in the provision of both the excitation light and reference light to common optical guide 10 or 32, col.5, lines 50-52, col.8, lines 52-54), a single image sensor (e.g. 12, Fig.5) at the distal end of an endoscope (Fig.5) that detects an autofluorescence image and color image (col.8, lines 54-57, and a data processor (20) that processes the autofluorescence image and color image to produce a processed image (e.g., col.6, lines 34-39).

Although Palcic et al. suggests that a laser can be used to provide the excitation light (col.4, lines 61-62), this reference does not provide the specifics of the light source, i.e., that it includes a diode laser and a second light source. Imaizumi et al. teaches that the use of two light sources, one being a diode laser, for a fluorescent endoscope system has been contemplated as one of numerous light source arrangements for providing both a reference light and an excitation light (note col.15, lines 8-13). The Examiner takes the position that since Palcic et al. does not provide specifics for the light source, it would be left up to the skilled artisan to use teachings in the prior art to fill in the gaps when reducing the Palcic et al. device to practice. Hence, it would have been obvious to one of ordinary skill in the art to have used a known prior art light source, the one described by Imaizumi et al. for example, functioning in a similar manner as Palcic et al. requires, to meet the objectives of the Palcic et al. device.

As to claim 38, note col.6, lines 35-60 and col.10, lines 29-39.

As to claims 39 and 46 (as renumbered), note col.3, lines 47-51.

As to claim 40, CCDs used in the Palcic et al. invention are color CCDs since they are capable of producing multicolored images (e.g., col.9, lines 37-43).

As to claim 41, note optical fiber bundle (10,32).

As to claim 43 (as renumbered), the lights are transmitted simultaneously (e.g. col.7, lines 23-25).

As to claim 45 (as renumbered), since the excitation light and reference lights share a common optical path, they have the same angular orientation.

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12. Claim 47 (as renumbered) is rejected under 35 U.S.C. 103(a) as being unpatentable over Palcic et al. in view of Imaizumi et al., as described above, and further in view of Perelman et al. (U.S. Pat. 6,091,984).

Palcic et al. teach a device that uses, for example a CCD, for the image sensor but fails to disclose all other known image sensors that can alternatively used. Perelman et al. teaches what is known by all of those of ordinary skill—the alternative use of either a CCD or CMOS image sensor (note col. 4, lines 26-34). CMOS technology is not new and in certain arrangements has cost advantages and improved functionality over CCD technology. It would therefore have been obvious to one of ordinary skill in the art to have used a CMOS image sensor instead of a CCD image sensor for the reasons set forth above.

13. Claim 48 (as renumbered) is rejected under 35 U.S.C. 103(a) as being unpatentable over Palcic et al. in view of Imaizumi et al. and further in view of Poindexter et al. (U.S. Pat. 5,979,423).

Palcic et al., as modified above, fails to disclose that the laser diode is of any particular type. Gallium nitride diode lasers with operate in the ultraviolet to blue wavelengths are well known and conventional in the art. Poindexter et al. is just one example of a teaching that a gallium nitride diode laser is a suitable source of excitation light (note col.2, lines 57-67). It would have been obvious to one of ordinary skill in the art to have used any known suitable diode laser light source as the diode laser light source taught by the Palcic et al./Imaizumi et al. device.

14. Claims 49 and 50 (as renumbered) are rejected under 35 U.S.C. 103(a) as being unpatentable over Palcic et al. in view of Imaizumi et al. and further in view of Groner et al. (U.S. Pat. 6,104,939).

Palcic et al. fails to disclose any particular light source for the reference light and Imaizumi et al. mentions a halogen light source *as an example*. Groner et al. also teaches use of a halogen light source in addition to many alternatives including a mercury arc lamp and a laser diode (col. 24, line 55 to col.25, line 4). It would have been obvious to one of ordinary skill in the art as a matter of design choice to use any known alternative type of light source as taught by Groner et al. for the reference light source of Palcic et al.

# Response to Amendment

15. The declaration under 37 CFR 1.132 filed December 23, 2009 is sufficient to overcome the rejection of claims 1-11 and 21-26 based upon insufficiency of disclosure under 35 USC 112, first paragraph. Said declaration (in addition to Applicant's arguments) has caused the Examiner to realize that, whether or not the diode laser was part of Applicant's invention, the laser diode is still specifically mentioned in the specification and could be construed as a potential UV source for excitation. One of ordinary skill would have recognized its potential use for any mention of a generic UV excitation source in the disclosure even if it is not labeled as a "preferred embodiment" or specifically described in connection with an particular embodiment mentioned in the Detailed Description. Furthermore, there is no rule that prevents Applicant from claiming any details from the specification, whether known in the prior art or not. Therefore, the Examiner has withdrawn the rejection.

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The declaration under 37 CFR 1.132 filed December 23, 2009 is insufficient to overcome the rejection of claim 7 based upon insufficiency of disclosure under 35 USC 112, first paragraph. The Examiner understands that the reference light can be derived from white light (which comprises red, green and blue wavelengths) but the specification fails to disclose that all three of these wavelengths are transmitted simultaneously with the excitation light, as claimed.

# Response to Arguments

16. Applicant's arguments filed November 20, 2009 and December 23, 2009 have been fully considered but they are not persuasive.

In view of Applicant's arguments and the declaration filed under 37 CFR 1.132, the Examiner has withdrawn the rejection of claims 1-11 and 21-26 based upon insufficiency of disclosure under 35 USC 112, first paragraph.

After consideration of Applicant's arguments and the evidence provided in the declaration filed under 37 CFR 1.132, the rejection of claim 7 under 35 USC 112, first paragraph is being maintained. Note additional comments regarding this issue in numbered paragraphs 4 and 15 above.

Regarding the rejection of the claims over Kaneko in view of Poindexter, Applicant offers no new arguments for those previously presented. Accordingly, the Examiner maintains his position with respect to the rejection using these references.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John P. Leubecker/ Primary Examiner Art Unit 3739

jpl